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its "teachings" inappropriately. Simply because L'Esperance makes mention of "energy absorbing compounds," does not mean that they are used for any visualization purposes. Indeed, the device of L'Esperance is not a punctum plug at all, but rather, is a drainage device inserted through a hole in the cornea. It appears to the undersigned that the "energy absorbing compounds" are used to control the flow of fluid, and have nothing to do with visualization. Accordingly, L'Esperance does not "anticipate the limitations of the instant claims," as the Examiner suggests. With regard to claim 2, whereas Applicant's substance is disposed on an outwardly exposed surface, just because L'Esperance has an outwardly exposed surface does not mean any of the compounds that the Examiner alludes are disposed at that location. The same argument holds true with respect to Figure 3. As regards Figure 4, none of the substances listed by Applicant are found in L'Esperance. Claim 5 includes the limitation of illumination wavelength in the violet or ultraviolet portion of the spectrum. Applicant cannot understand why this claim was rejected, since the Examiner makes no argument.

Claims 1-8 stand rejected over Sedar et al., U.S. Patent No. 4,959,048, or Freeman, U.S. Patent No. 3,949,750, in view of Gwon et al., U.S. Patent No. 5,178,635. Sedar resides in a lacrimial duct occluder, having "an outwardly exposed surface," but that is about the only similarity whatsoever to the instant invention. Freeman is directed to a punctum plug and method for treating keratoconjunctivitis sicca (dry eye) and other ophthalmic ailments. Again, Freeman includes "an outwardly exposed surface," but this is not Applicant's point of novelty. All "plugs" have an outwardly exposed surface, even wine corks. But unless such devices have the rest of Applicant's limitations in combination, rejection is unsupported.

Gwon et al. resides in a method for determining an amount of medication in an implantable device. It has nothing to do with punctum plugs in particular or plugs in general, but rather, uses a particular shape in the form of an annulus. Despite the Examiner's argument that "Gwon is merely used to show that suitable dyes and fluorescent traces have been used in the art as a means for improving visualization and ophthalmic devices," there is no teaching or suggestion *from the prior art* to support the Examiner's position. In rejecting claims under 35 U.S.C. §103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. See In Re Fine, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the Examiner is expected to make the factual determinations set forth in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 5569, 467

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(1966), and to provide a reason why one having ordinary skill in the pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reason must stem from some teaching, suggestion or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. <u>Uniroyal Inc. v. Rudkin-Wiley Corp.</u>, 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir.), <u>cert. denied</u>, 488 U.S. 825 (1988); <u>Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.</u>, 776 F.2d 281, 293, 227 USPQ 657,664 (Fed. Cir. 1985), <u>cert. denied</u>, 475 U.S. 1017 (1986); <u>ACS Hospital Systems, Inc. v. Montefiore Hospital</u>, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). These showings by the Examiner are an essential part of complying with the burden of presenting a <u>prima facie</u> case of obviousness. <u>Note In Re Oetiker</u>, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

Based upon the foregoing, Applicant believes all claims are in condition for allowance.

Respectfully submitted,

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Date: May 27, 2003

## **CERTIFICATE OF MAILING (37 CFR 1.8(a))**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date indicated below and is addressed to: Mail Stop Petitions, Commissioner for Patents, PO 1450, Alexandria, VA 22313-1450.

Date: May 27, 2003

GIFFORD, KRASS, GROH, SPRINKLE, ANDERSON & CITKOWSKI, P.C.

Sheryl L. Hammer